REMARKS

This amendment is responsive to the Office Action dated July 12, 2005. Applicant has amended claims 1, 2, 4, 6, 7, 9, 11, 14, 16, 22 and 23. Applicant has amended claims 1, 2, 4, 6, 7, 9, 11, 14, 22 and 23 for purposes of clarification, i.e., for reasons unrelated to patentability. Claims 1-23 remain pending.

Information Disclosure Statement

In the Office Action, the Examiner indicated that the Information Disclosure Statement filed 10-28-04 in part failed to comply with the provisions of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609, because the date for certain internet publications cited therein was not supplied. Under separate cover, Applicant submits a supplemental Information Disclose Statement citing the internet publications which have not yet been considered as to the merits by the Examiner because of failure to supply the date. In the supplemental Information Disclosure Statement, Applicant supplies the date which the publications were first downloaded by Applicant's representative. Applicant respectfully requests that the Examiner consider the cited references.

Claim Rejection Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More particularly, the Examiner found that recitation in claim 16 of "the flexible tether member" lacked antecedent basis. Applicant has amended claim 16 to depend from claim 15, which recites "a flexible tether member," and thereby provides antecedent basis for the recitation of "the flexible tether member" in claim 16. Applicant submits that claim 16, as amended, particularly points out and distinctly claims the subject matter, as required by 35 U.S.C. 112, second paragraph.

Claim Rejections Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 2, 5-10 and 17-21 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,645,586 to Meltzer (Meltzer). Applicant respectfully traverses these rejections to the extent such rejection may be considered applicable

to the amended claims. Meltzer fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Independent claim 1

For example, Meltzer fails to teach or suggest a flexible overmold that covers a second module and partially covers a first module wherein the first module housing extends out of the overmold, as required by Applicant's independent claim 1, as amended. With respect to this requirement of claim 1, the Examiner stated that the biocompatible polymer coating discussed at col. 4, ll. 44-49 of Meltzer "is considered to anticipate the claimed overmold because both materials are flexible enough to allow for easy manipulation during implantation such that they allow the implantable device to conform to the cranium or other body part." This statement is incorrect for several reasons.

First, the Examiner's statement implies that Meltzer teaches cranial implantation of the disclosed device. However, Meltzer does not even suggest cranial implantation of the disclosed device. Instead, Meltzer describes a defibrillator implanted in the thoracic cavity.

Further, whether the Meltzer coating is "flexible enough to allow for easy manipulation during implantation such that they allow the implantable device to conform to the cranium or other body part," is entirely irrelevant. "[F]lexible enough to allow for easy manipulation during implantation such that they allow the implantable device to conform to the cranium or other body part," is not a requirement of claim 1. Instead, as stated above, claim 1 requires "a flexible overmold that covers a second module and partially covers a first module wherein the first module housing extends out of the overmold." Meltzer fails to teach or suggest this requirement of claim 1.

Meltzer teaches only two ways in which the disclosed biocompatible polymer may be configured. First, Meltzer teaches that the entire housing 38, including the entirety of segments 23-25, may be coated with the biocompatible polymer layer.[1] In this first configuration, none of the segments would be partially covered by the polymer layer, or extend out of the polymer layer, as required by claim 1. As the only alternative, Meltzer teaches that the housing segments

[1] Meltzer, col. 4, ll. 44-45.

23-25 may have individual seals only at the point where an interconnect merges therefrom.[2] In this alternative configuration, none of the individual seals would both cover a first segment and partially cover a second segment, as required by claim 1.

Meltzer does not provide any teaching that would have suggested any modification of these two configurations, much less provide any teaching that would have suggested modification to achieve an overmold that covers a second module and partially covers a first module wherein the first module housing extends out of the overmold, as required by claim 1. Further, the other reference cited by the Examiner, U.S. Patent No. 6,176,879 to Reischl et al., does not provide any teaching that would have suggested this requirement of claim 1 to one of ordinary skill in the art.

Claims 2 and 7

As other examples, claim 2 requires that the first module housing is substantially cylindrical, while claim 7 requires that the first module housing and a third module housing are each substantially cylindrical. Directly contrary to these requirements of claims 2 and 7, Meltzer discloses housing segments 23-25 that are hexahedral or "cube-like."[3] Meltzer does not disclose or suggest any other shape for the housing segments, much less cylindrical housing segments. In fact, because Meltzer teaches hexahedral housing segments that are maintained in close proximity and connected along their adjacent sides by a hinge or other mechanism, one of ordinary skill would have consciously avoided modification of the Meltzer housing segments to be substantially cylindrical. Such a modification of the Meltzer housing segments would have deprived the Meltzer device of the closely proximate adjacent sides desired for the described housing segment connections.

In support of the rejections of claims 2 and 7, the Examiner cited col. 4, ll. 1-9 of Meltzer. The cited portion of Meltzer teaches that the hexahedral housing segments include complementary cylindrical terminating portions that combine to form a hinge between the segments. However, this teaching of a cylindrical portion attached to an otherwise hexahedral

[2] Meltzer, col. 4, ll. 46-48.
[3] Meltzer, FIG. 2.

housing is irrelevant to the requirements in claims 2 and 7 of housings that are substantially cylindrical.

Claim 21

The Examiner either overlooked, or misunderstood the requirements of claim 21. Claim 21 requires that the overmold is shaped for implantation on a cranium of a patient. Meltzer provides no teaching regarding either the shape of the biocompatible polymer described at col. 4, ll. 44-48, or implantation of the device described therein on the cranium. Accordingly, Meltzer fails to teach or suggest this requirement of claim 21.

In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[4] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(b) is improper. [5]

Meltzer fails to disclose each and every limitation set forth in claims 1, 2, 5-10 and 17-21. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1, 2, 5-10 and 17-21 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

Claim Rejections Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 3, 4 and 11-16 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer in view of U.S. Patent No. 6,176,879 to Reischl et al. (Reischl), and rejected claims 22 and 23 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer. Applicant respectfully traverses these rejections to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or

[4] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[5] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Initially, Applicant notes that Reischl fails to provide any teaching that would overcome the deficiencies of Meltzer with respect to the requirements of Applicant's independent claim 1 discussed above. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 3, 4 and 11-16 under 35 U.S.C. § 103(a), and the rejections of each of these claims should be withdrawn. Moreover, the applied references, either alone or in combination, fail to teach or suggest a number of the requirements recited in claims 3, 4, 11-16, 22 and 23.

Claim 14

As amended, claim 14 requires a recharge coil that substantially encircles a first module. As acknowledged by the Examiner, Meltzer fails to teach or suggest a recharge coil. Reischl discusses a recharge coil, but does not teach or suggest that the recharge coil substantially encircles another module of a medical device, as required by claim 14. Instead, as clearly shown in FIG. 2, Reischl teaches locating a recharge coil 26 in a separate, ceramic housing portion 12, away from the other device components.[6] Because Reischl teaches that locating a recharge coil 26 in this manner is an advantage of their invention, Reischl would have taught away from any modification of Meltzer to include a recharge coil that substantially encircles a first module, as required by claim 14.

In other words, even when combined, the cited references fail to teach or suggest a recharge coil that substantially encircles a first module, as required by claim 14. For at least this reason, the Examiner has failed to establish a prima facie case for the non-patentability of claim 14.[7] Further, although the Examiner attempted to identify a general motivation for including a recharging coil as taught by Reischl in the device taught by Meltzer, the Examiner failed to identify any motivation for modification of the device taught by Meltzer to include a recharge coil that substantially encircles a first module of the device. Indeed, the secondary reference cited by the Examiner, Reischl, teaches away from the modification of Meltzer required to arrive

[6] *See also* Reischl, col. 3, ll. 35-63.
[7] *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

at Applicant's claimed invention. For at least this additional reason, the Examiner has failed to establish a prima facie case for the non-patentability of claim 14.[8]

Claim 16

As another example, claim 16 requires an implantable medical device comprising a third module located outside of an overmold, and a flexible tether member that connects the third module to the overmold, wherein the flexible member comprises a helix. The Examiner appears to have overlooked the requirements of claim 16. Neither Meltzer nor Reischl provides any teaching or suggestion of a helix. Applicant respectfully requests that the Examiner consider the requirements of claim 16.

Claims 22 and 23

As other examples, claim 22 and independent claim 23 both require an implantable medical device in which the height of a first module housing, which extends out of an overmold for receipt in a recess in a cranium of a patient, is greater than the height of a second module housing. The Examiner acknowledged that Meltzer does not teach, or even suggest module housings with different heights. However, the Examiner argued that it would have been an obvious matter of design choice to change the housing heights of Meltzer to meet the requirements of claims 22 and 23, "since [A]pplicant has not disclosed the height differences solve any stated problem or is for any particular purpose...."

Applicant respectfully directs the Examiner to the Summary of the present Application, which at paragraph [0008] states:

> The module(s) covered by the overmold may be implanted between the cranium and scalp while the module(s) partially covered by the overmold may be placed at least partially into a recess in the cranium. Components of the implantable medical device that may take up more space may be in the partially covered module since that module may be larger. Smaller components may be in the module(s) covered by the overmold.

Applicant also respectfully directs the Examiner to paragraph [0066] of the present Application, which states:

---

[8] *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

> Embodiments in which overmold 92 fully encapsulates modules 30, 32 and 34 may be preferred as providing greater patient comfort and protection of the modules. However, in some embodiments in which portions 110, 112 and 114 are exposed, troughs may be drilled into the surface of cranium 12 that are sized to receive the portions. By recessing portions 110, 112 and 114 into such troughs, the height of modular IMD 90 above cranium 12 may be reduced.

As indicated by these passages, one advantage that may result from an implantable medical device in which one module has a height greater than another is the ability to distribute internal device components amongst the modules according to size. The "smaller" module may contain smaller components, and be covered by an overmold for, among other reasons, patient comfort and protection, while the "larger" module may contain larger components, and extend out of the overmold. The larger module (greater height) may extend into a recess in the cranium of a patient, which may allow the overall height of the implantable medical device to be reduced and consistent across the modules.

It is well established that the Examiner bears the burden of establishing a prima facie case of obviousness.[9] In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention.[10] A prima facie case of obviousness is established only when this burden is met.

Neither Meltzer, nor any other cited reference, provides any teaching that would have suggested the desirability of modification of the Meltzer housing segments to have different heights, much less modification such that a first module housing, which extends out of an overmold for receipt in a recess in a cranium of a patient, is greater than the height of a second module housing, as required by claims 22 and 23. Accordingly, without access to Applicants' disclosure, one of ordinary skill in the art would have had no appreciation of the desirability of such modification.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 3, 4, 11-16, 22 and 23 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

---

[9] *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).
[10] *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995).

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 11/14/05

By: _____

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Jason D. Kelly
Reg. No.: 54,213